



PATENT

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

| | | | |
|-----------------|--|------------------|-------|
| Applicant: | Alex C. Toy; John W. Forsberg | Confirmation No. | 9367 |
| Serial No.: | 10/693,012 | | |
| Filed: | October 24, 2003 | Customer No.: | 28863 |
| Examiner: | Darin Roberts | | |
| Group Art Unit: | 3762 | | |
| Docket No.: | 1023-288US01 | | |
| Title: | MEDICAL DEVICE PROGRAMMER WITH REDUCED-NOISE POWER SUPPLY | | |

DECLARATION UNDER 37 C.F.R. 1.132

Commissioner for Patents
P.O. Box 1450
Alexandria, VA 22313-1450

We, Alex C. Toy and John W. Forsberg, declare as follows:

1. We are named inventors in above-referenced Patent Application Serial No. 10/693,012.
2. We are employees of Medtronic, Inc., the Assignee of record for the present application.
3. The above-referenced Patent Application Serial No. 10/693,012 claims priority to Provisional Patent Application Serial No. 60/508,511 filed October 2, 2003.
4. More than one year prior to October 2, 2003, Medtronic, Inc. requested that Benchmark Electronics, Inc. manufacture 222 programmers for a medical device pursuant to assembly drawings shown in Exhibit A. Exhibit A is a two-page document assigned document number 502814 and relates to a programmer with model number 37741 ("Model 37741

programmer”). On sheet 1, Exhibit A illustrates an assembly view of a Model 37741 programmer for a medical device. On sheet 2, Exhibit A illustrates an assembled view of a Model 37741 programmer for a medical device. Medtronic Inc. confidential and proprietary information has been redacted from Exhibit A.

5. More than one year prior to October 2, 2003, Benchmark Electronics, Inc. manufactured 222 Model 37741 programmers pursuant to the request from Medtronic, Inc.

6. At least 89 of the 222 Model 37741 programmers manufactured by Benchmark Electronics, Inc. more than one year prior to October 2, 2003 were used for experimental purposes, as evidenced by Exhibits B-D. Exhibit B is a forty-nine page document assigned document number 288117-70205 and entitled, “Neuro Patient Programmer Platform Electrical DVT Report.” Exhibit C is a one page screen print of an internal electronic document storage and retrieval system at Medtronic, Inc., which indicates that document number 288117-70205 (Exhibit B) was modified on October 7, 2002 and June 28, 2003. Exhibit D is a twenty-nine page document entitled, “DVT Test Data for 288117-70020,” and summarizes the results of tests conducted in May 2002 and June 2002. Medtronic Inc. confidential and proprietary information has been redacted from Exhibits B and D.

7. The remainder of the 222 Model 37741 programmers manufactured by Benchmark Electronics, Inc. more than one year prior to October 2, 2003 were not used for the tests reflected in Exhibits B and D and were used internally by Medtronic, Inc. employees for development purposes.

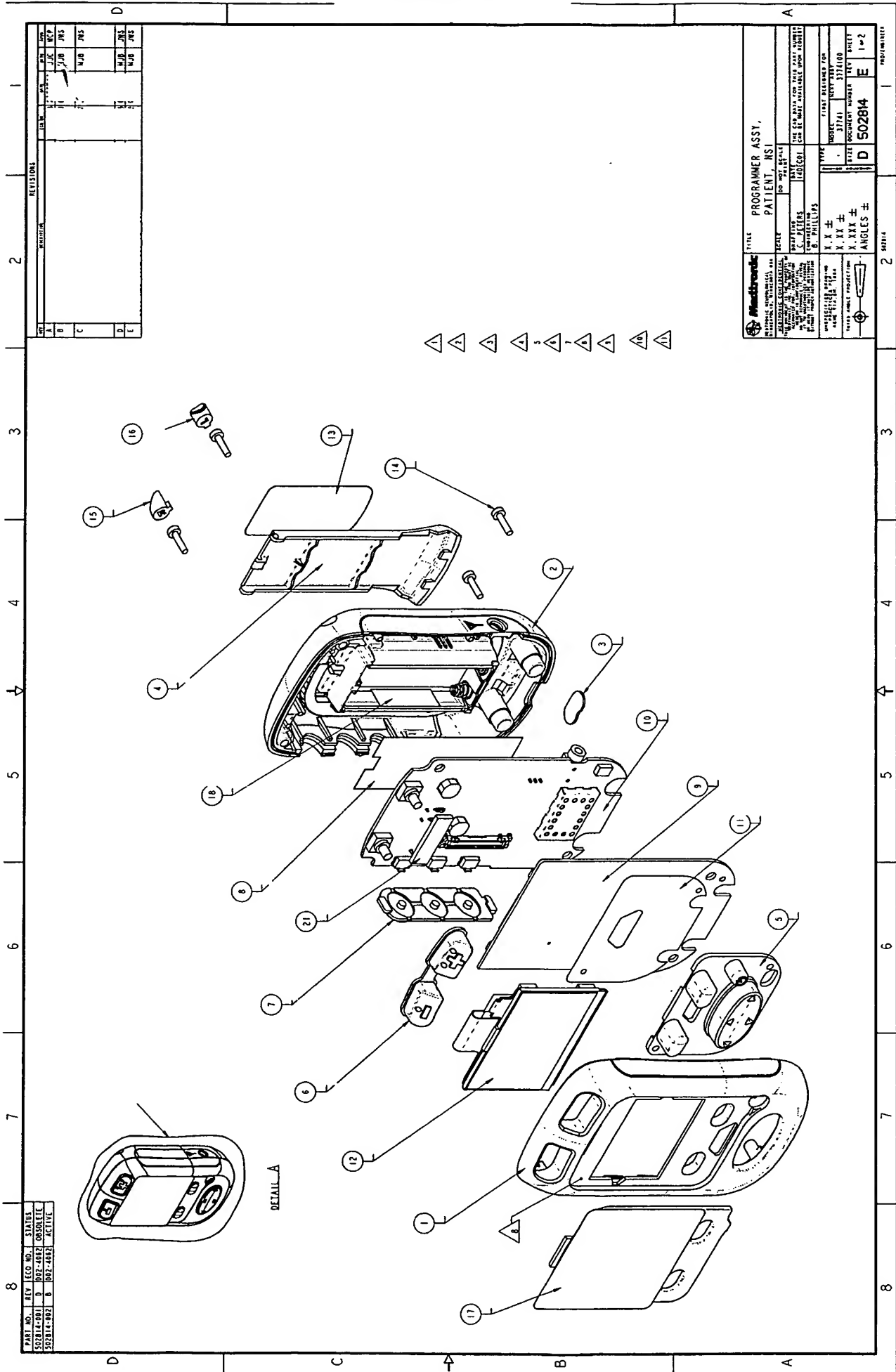
8. In view of this Declaration and the content of Exhibits A-D, it is clear that the 222 Model 37741 programmers manufactured by Benchmark Electronics, Inc. were not “in public use or on sale in this country, more than one year prior to the date of application for patent in the United States” under 35 U.S.C. § 102(b).

We hereby declare that all statements made herein of my own knowledge are true and that all statements made on information and belief are believed to be true; and further that these statements were made with the knowledge that willful false statements and the like so made are punishable by fine or imprisonment, or both, under Section 1001 of Title 18 of the United States Code and that such willful false statements may jeopardize the validity of the application or any patent issued thereon.

Date: Oct. 4, 2006 Signed: Alex C. Toy
Alex C. Toy

Date: Oct 4, 2006 Signed: John W. Forsberg
John W. Forsberg

EXHIBIT A



| PART NO. | REV | ECO NO. | STATUS |
|------------|-----|----------|----------|
| 502814-001 | 0 | 002-4082 | OBsolete |
| 502814-002 | 0 | 002-4082 | ACTIVE |

| REVISIONS | | DATE | BY | CHKD | APP'D |
|-----------|--|----------|-----|------|-------|
| A | | 11/11/81 | JJC | JMS | |
| B | | 11/11/81 | JJC | JMS | |
| C | | 11/11/81 | JJC | JMS | |
| D | | 11/11/81 | JJC | JMS | |

| | | | |
|---|--|---|--|
| Metronics MEDICAL ELECTRONICS 1000 N. 10TH ST., SUITE 100 DENVER, CO 80202 (303) 733-1111 | | TITLE: PROGRAMMER ASST., PATIENT, MSI SCALE: 1:1 DATE: 11/11/81 C. PETERS B. PHILLIPS | |
| FIRST RELEASED FOR: 11/11/81 SECOND RELEASED FOR: 11/11/81 THIRD RELEASED FOR: 11/11/81 FOURTH RELEASED FOR: 11/11/81 FIFTH RELEASED FOR: 11/11/81 SIXTH RELEASED FOR: 11/11/81 SEVENTH RELEASED FOR: 11/11/81 EIGHTH RELEASED FOR: 11/11/81 NINTH RELEASED FOR: 11/11/81 TENTH RELEASED FOR: 11/11/81 | | TYPE: D SIZE: 502814 ANGLE: 1-2 | |

EXHIBIT A (cont.)

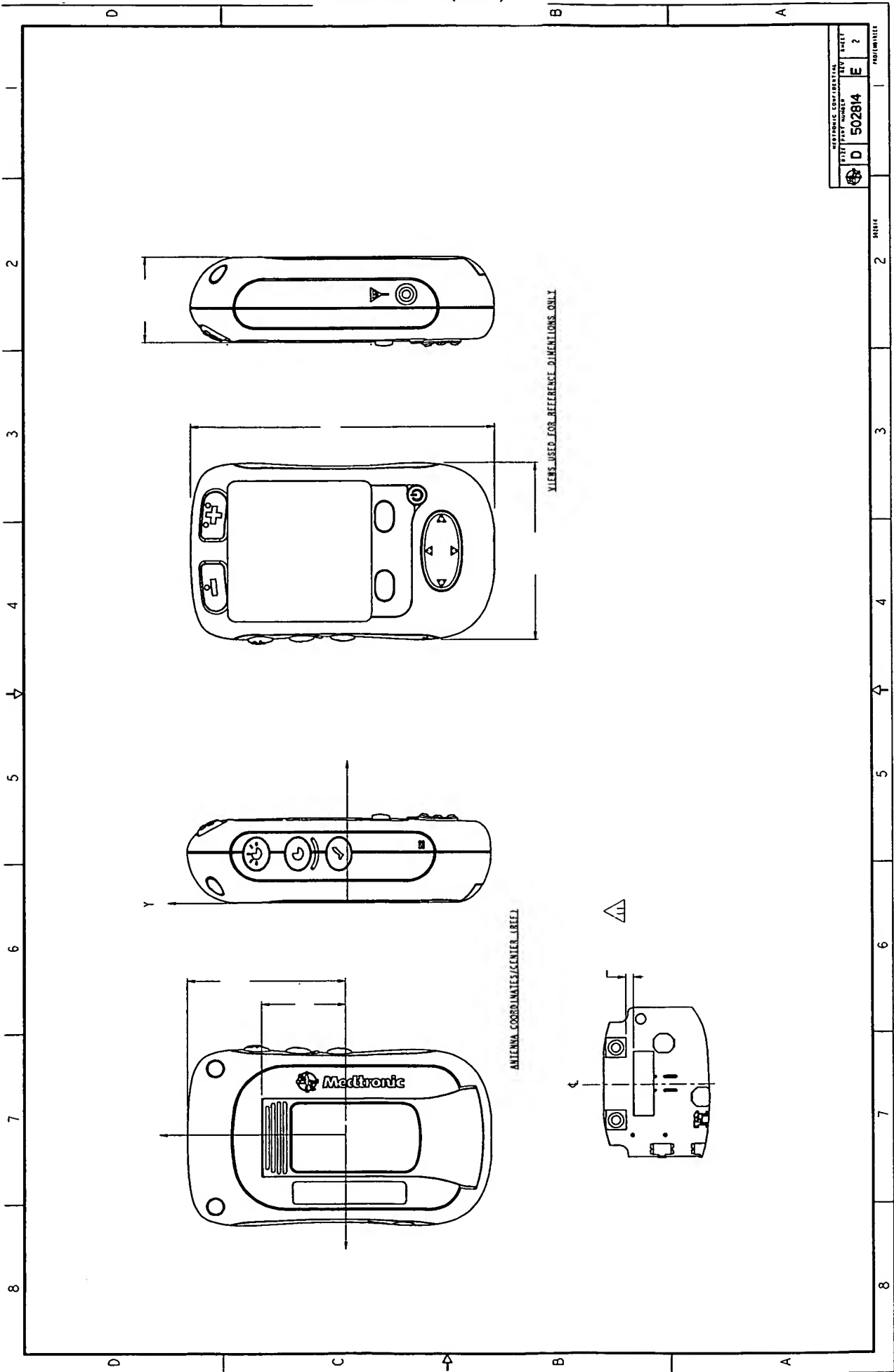




EXHIBIT B

| | | | | | |
|---|------------------|---------------------|--|---------------------------|-----------------------|
|  | Medtronic | <i>Neurological</i> | Document Number 288117-70205 | Rev/Version 1.0 | Sht 1 of 49 |
| Title: Neuro Patient Programmer Platform Electrical DVT Report | | | | | |

Revision History:


| Revision | Comments |
|----------|-----------------------------|
| 1.0 | Initial release for routing |

EXHIBIT B (cont.)

| | | | | | |
|---|------------------|---------------------|---|----------------------------------|------------------------------|
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1 INTRODUCTION

This document is the electrical Design Verification Test (DVT) Report for the 37741 Patient Programmer Platform.

1.1 Purpose

The purpose of this report is to document the results of test plan

1.2 Scope


This report applies only to design verification testing of the 37741 Patient Programmer Platform.

1.3 Document Overview

This document is organized as follows:

- Section 2 contains references and definitions.
- Section 3 contains a table with the list of tests, software revisions, sample sizes, and test results.
- Section 4 contains the results of the electrical design verification tests.

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2 REFERENCES AND DEFINITIONS

This section identifies internal and external reference documents that augment the information provided in this document. It also defines terms, acronyms, and abbreviations used within the document.

2.1 Internal Medtronic References

| Number | Name |
|--------------|------|
| 120275 | |
| 215387 | |
| 288117-70040 | |
| 288117-70044 | |
| 288117-70029 | |
| 503011001 | |
| 288117-70200 | |

Note: Document revisions referenced in DVT Plan.

2.2 External References

Reference the PEM Electrical Specification for external specification standards.

2.3 Definitions, Acronyms, and Abbreviations

ARB: Arbitrary Waveform Generator

ARB equipment: One or more arbitrary waveform generators, used alone or in conjunction to generate sophisticated waveforms.

DUT: Device Under Test

DVT: Design Verification Test

DVT Console: The test console needed to perform the tests specified herein.

ES: Electrical Specification #120275


GPB: General Purpose Interface Bus

PEM: Patient Electronic Module

PP: Patient Programmer

POR: Power On Reset

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| | | | | |
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3 Test Results Summary


Table 1 summarizes the results of all electrical design verification testing. Section 4 details each test setup, criteria, and results.

- Test data is stored as 288117-70200.
- Table 1 indicates test name, sample size, DUT software revision, Test Script Software revision, test path, and results.
- Test paths are shown in section 3.1.

Table 1

| Test Name | Sample Size | DUT Software Revision | Script Software Test Revision | Test Path | Results |
|-----------|-------------|-----------------------|-------------------------------|-----------|---------|
| | 22 | | | | PASS |
| | 22 | | | | PASS |
| | 22 | | | | PASS |
| | 22 | | | | PASS |
| | 22 | | | | PASS |
| | 22 | | | | PASS |
| | 22 | | | | PASS |
| | 22 | | | | PASS |
| | 22 | | | | PASS |
| | 22 | | | | PASS |
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| | 22 | | | | PASS |
| | 22 | | | | PASS |
| | 22 | | | | PASS |
| | 22 | | | | PASS |
| | 22 | | | | PASS |
| | 22 | | | | PASS |
| | 1 | | | | PASS |

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| | | | | |
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3.1 Test Paths

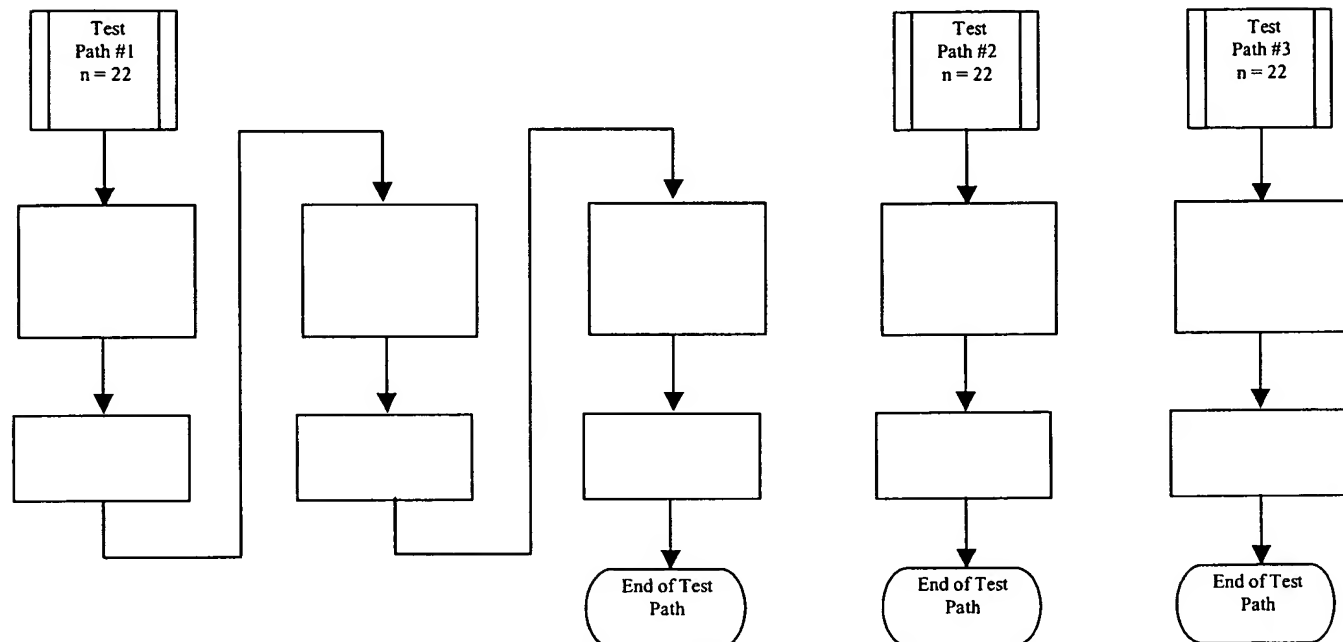



EXHIBIT B (cont.)

| | | | | | |
|---|------------------|---------------------|---------------------------------|--------------------|----------------|
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4 ELECTRICAL TESTS

This section specifies electrical tests performed on the 37741 Patient Programmer Platform.

4.1 Power Source Tests**4.1.1 Current Drain Test****4.1.1.1 Objective**

To verify the current drain meets the requirements specified in the *Power Source* section of the PEM Electrical Specification.

4.1.1.2 Method and Equipment**4.1.1.3 Test Cases**

There are _ test cases for transmit using all combinations of test values below:

| Parameter | Test Values | Units |
|-----------|-------------|-------|
| | | |
| | | |
| | | |
| | | |

The

There are test cases using all combinations of test values below:

| Parameter | Test Values | Units |
|-----------|-------------|-------|
| | | |
| | | |
| | | |
| | | |


There are test cases using two combinations of test values below:

| Parameter | Test Values | Units |
|-----------|-------------|-------|
| | | |
| | | |
| | | |
| | | |

There are total test cases.

4.1.1.4 Acceptance Criteria

EXHIBIT B (cont.)

| | | | | |
|--|--------------|---------------------------------|--------------------|----------------|
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| Operating Condition (Ref.) | Antenna | Duty Cycle (%) | Current Drain (mA) MAX | | |
|-------------------------------|---------|----------------|---------------------------|---|---|
| | | | V | V | V |
| Row A | INT | | | | |
| Row B | INT | | | | |
| Row C | INT | | | | |
| Row D | INT | | | | |
| Row E | INT | | | | |
| Row F | INT | | | | |
| Row G | INT | | | | |
| Row H | EXT | | | | |
| Row I | INT | | | | |
| Row J | INT | | | | |

Note 1:

4.1.1.5 Test Setup

- 1.
- 2.
- 3.

4.


4.1.1.6 Test Procedure

- 1.
- 2.

3.

4.

EXHIBIT B (cont.)

| | | | | |
|--|---------------------|--|---------------------------|-----------------------|
|  Medtronic | <i>Neurological</i> | Document Number 288117-70205 | Rev/Version 1.0 | Sht 9 of 49 |
| Title: Neuro Patient Programmer Platform Electrical DVT Report | | | | |

4.1.1.7 RESULTS **PASS**

All devices met the acceptance criteria.

| Operating Condition | Current Drain (mA) MAX | | | | | | | | | | | | | | | | | |
|---------------------|---------------------------|-----|-----|------|---------|--|------|-----|-----|------|---------|--|------|-----|-----|------|---------|--|
| | | | | | | | | | | | | | | | | | | |
| Row | Spec | Min | Max | Mean | Std Dev | | Spec | Min | Max | Mean | Std Dev | | Spec | Min | Max | Mean | Std Dev | |
| A | | | | | | | | | | | | | | | | | | |
| B | | | | | | | | | | | | | | | | | | |
| C | | | | | | | | | | | | | | | | | | |
| D | | | | | | | | | | | | | | | | | | |
| E | | | | | | | | | | | | | | | | | | |
| F | | | | | | | | | | | | | | | | | | |
| G | | | | | | | | | | | | | | | | | | |
| H | | | | | | | | | | | | | | | | | | |
| I | | | | | | | | | | | | | | | | | | |
| J | | | | | | | | | | | | | | | | | | |

4.1.2 **Supply Voltage Range Test**


4.1.2.1 Objective

To verify the supply voltage range meets the requirements specified in the *Power Source* section of the PEM Electrical Specification.

4.1.2.2 Method and Equipment

4.1.2.3 Test Cases

EXHIBIT B (cont.)

| | | | | |
|--|---------------------|---------------------------------|--------------------|-----------------|
|  Medtronic | <i>Neurological</i> | Document Number 288117-70205 | Rev/Version 1.0 | Sht 10 of 49 |
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| Parameter | Test Values | Units |
|-----------|-------------|-------|
| | | |
| | | |
| | | |

The

There is test case without transmit:

| Parameter | Test Values | Units |
|-----------|-------------|-------|
| | | |
| | | |
| | | |

4.1.2.4 Acceptance Criteria

| Operating Condition | Antenna | H-Bridge Drive Duty Cycle (%) | Min operating voltage (V) |
|---------------------|---------|-------------------------------|---------------------------|
| | | | |


4.1.2.5 Test Setup

- 1.
- 2.
- 3.
- 4.

4.1.2.6 Test Procedure

- 1.
- 2.
- 3.

EXHIBIT B (cont.)

| | | | | | |
|---|------------------|---------------------|--|---------------------------|------------------------|
|  | Medtronic | <i>Neurological</i> | Document Number 288117-70205 | Rev/Version 1.0 | Sht 11 of 49 |
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4.1.2.7 RESULTS PASS

All devices met the acceptance criteria.

| Operating Condition | Antenna | Supply Voltage Range (Volts) | | | | |
|---------------------|---------|------------------------------|-----|-----|---------|--|
| | | Min | Max | Avg | Std Dev | |
| | | | | | | |
| | | | | | | |
| | | | | | | |

4.2 Input/Output Connections Tests**4.2.1 Keypad Interface Test****4.2.1.1 Objective**

To verify the keypad interface meets the requirements specified in the *Input/Output Connections* section of the PEM Electrical Specification.

4.2.1.2 Method and Equipment**4.2.1.3 Test Cases**


| Parameter | Test Values | Units |
|-----------|-------------|-------|
| | | |

4.2.1.4 Acceptance Criteria**4.2.1.5 Test Setup**

- 1.
- 2.
- 3.

4.2.1.6 Test Procedure

EXHIBIT B (cont.)

| | | | | |
|--|---------------------|--|---------------------------|------------------------|
|  Medtronic | <i>Neurological</i> | Document Number 288117-70205 | Rev/Version 1.0 | Sht 12 of 49 |
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3.

4.2.1.7 RESULTS PASS

All devices met the acceptance criteria.

| Tests | Keypad Interface (pass/fail) | | |
|-------|------------------------------|------|------|
| | | | |
| | Pass | Pass | Pass |
| | Pass | Pass | Pass |

4.2.2 Display Interface Test**4.2.2.1 Objective**


To verify the display interface meets the requirements specified in the *Input/Output Connections* section of the PEM Electrical Specification.

4.2.2.2 Method and Equipment**4.2.2.3 Test Cases**

There are test cases using combinations of the test values below:

| Parameter | Test Values | Units |
|-----------|-------------|-------|
| | | |
| | | |
| | | |

EXHIBIT B (cont.)

| | | | | |
|--|--------------|---------------------------------|--------------------|-----------------|
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4.2.2.4 Acceptance Criteria

| Test Parameters | | | | Requirements | | | |
|-----------------|--|--|--|--------------|--|--|--|
| | | | | | | | |
| | | | | | | | |
| | | | | | | | |
| | | | | | | | |
| | | | | | | | |
| | | | | | | | |
| | | | | | | | |
| | | | | | | | |
| | | | | | | | |

4.2.2.5 Test Setup

- 1.
- 2.
- 3.

4.2.2.6 Test Procedure


- 1.
- 2.
- 3.
- 4.

4.2.2.7 RESULTS **PASS**

All devices met the acceptance criteria.

| Test | Display Interface (pass/fail) | | |
|------|-------------------------------|------|------|
| | | | |
| | Pass | Pass | Pass |
| | Pass | Pass | Pass |
| | Pass | Pass | Pass |

EXHIBIT B (cont.)

| | | | | |
|--|---------------------|---|----------------------------------|-------------------------------|
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4.2.3 External Antenna Interface Test

4.2.3.1 Objective

To verify the external antenna interface meets the requirements specified in the *Input/Output Connections* section of the PEM Electrical Specification.

4.2.3.2 Method and Equipment

4.2.3.3 Test Cases

There are test cases using all combinations of test values below:

| Parameter | Test Values | Units |
|-----------|-------------|-------|
| | | |

4.2.3.4 Acceptance Criteria


- When an external antenna is connected, there should be no downlink from the internal antenna.
- When an external antenna is connected, the uP should detect that the antenna is connected.

| External Antenna | | | | | Yes/No |
|------------------|-----|-----|-----|-----|--------|
| | Min | Max | Min | Max | |
| | | | | | |

4.2.3.5 Test Setup

- 1.
- 2.
- 3.
- 4.
- 5.

EXHIBIT B (cont.)

| | | | | |
|--|---------------------|--|---------------------------|------------------------|
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4.2.3.6 Test Procedure

1.

2.


3.

4.

4.2.3.7 RESULTS **PASS**

All devices met the acceptance criteria.

EXHIBIT B (cont.)

| | | | | |
|--|---------------------|--|---------------------------|------------------------|
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| Test Configuration | Test |
|--------------------|------|
| | A |
| | B |

| Test | External Antenna Interface (A/m) | | | | | | | | | | | | | |
|------|----------------------------------|-----|------|---------|-----|-----|------|---------|-----|-----|------|---------|--|--|
| | | | | | | | | | | | | | | |
| | Min | Max | Mean | Std dev | Min | Max | Mean | Std dev | Min | Max | Mean | Std dev | | |
| A | | | | | | | | | | | | | | |
| B | | | | | | | | | | | | | | |

4.2.4 Infrared Port Interface Test

4.2.4.1 Objective

To verify the infrared port interface meets the requirements specified in the *Input/Output Connections* section of the PEM Electrical Specification. [PTPROG_PEMT-0006:~]

4.2.4.2 Method and Equipment

4.2.4.3 Test Cases

There are test cases using all combinations of test values below:

| Parameter | Test Values | Units |
|-----------|-------------|-------|
| | | |


4.2.4.4 Acceptance Criteria

| | | |
|-----|-----|------|
| | | |
| All | All | None |

4.2.4.5 Test Setup

- 1.
- 2.

EXHIBIT B (cont.)

| | | | | | |
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3.

4.2.4.6 Test Procedure

1.

2.

3.

4.

4.2.4.7 RESULTS **PASS**

All devices met the acceptance criteria.

| Voltage (V) | Infrared (pass/fail) | | | | | | | | |
|-------------|----------------------|------|------|------|------|------|------|------|------|
| | | | | | | | | | |
| | | | | | | | | | |
| | Pass | Pass | Pass | Pass | Pass | Pass | Pass | Pass | Pass |
| | Pass | Pass | Pass | Pass | Pass | Pass | Pass | Pass | Pass |
| | Pass | Pass | Pass | Pass | Pass | Pass | Pass | Pass | Pass |

4.2.5 Audio Transducer Test

4.2.5.1 Objective


To verify the audio transducer meets the requirements specified in the *Input/Output Connections* section of the PEM Electrical Specification.

4.2.5.2 Method and Equipment

4.2.5.3 Test Cases

There are test cases using all combinations of test values below:

EXHIBIT B (cont.)

| | | | | |
|--|---------------------|--|---------------------------|------------------------|
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| Parameter | Test Values | Units |
|-----------|-------------|-------|
| | | |
| | | |

4.2.5.4 Acceptance Criteria

| | | | |
|--|--|--|--|
| | | | |
| | | | |

4.2.5.5 Test Setup

- 1.
- 2.
- 3.
- 4.
- 5.

4.2.5.6 Test Procedure

- 1.
- 2.
- 3.
- 4.

4.2.5.7 RESULTS **PASS**


All devices met the acceptance criteria.

| Audio Transducer (dB SPL) | | | | | | | | | | | | | | |
|---------------------------|-----|------|---------|--|-----|-----|------|---------|--|-----|-----|------|---------|--|
| | | | | | | | | | | | | | | |
| Min | Max | Mean | Std dev | | Min | Max | Mean | Std dev | | Min | Max | Mean | Std dev | |
| | | | | | | | | | | | | | | |
| | | | | | | | | | | | | | | |

4.2.6 Manufacturing/Test Interface Test

Manufacturing requirements defined in Test Specification, Patient Programmer, 215387.

EXHIBIT B (cont.)

| | | | | |
|--|---------------------|--|---------------------------|------------------------|
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| Title: Neuro Patient Programmer Platform Electrical DVT Report | | | | |

4.3 Internal Resources Tests**4.3.1 Memory Test****4.3.1.1 Objective**

To verify the internal memory resources meet the requirements specified in the *Internal Resources* section of the PEM Electrical Specification.

4.3.1.2 Method and Equipment**4.3.1.3 Test Cases**

There are test cases using all combinations of test values below:

| Parameter | Test Values | Units |
|-----------|-------------|-------|
| | | |

4.3.1.4 Acceptance Criteria

| | |
|-----|------|
| | |
| All | Pass |

4.3.1.5 Test Setup

- 1.
- 2.
- 3.

4.3.1.6 Test Procedure


- 1.
- 2.
- 3.
- 4.

4.3.1.7 RESULTS PASS

All devices met the acceptance criteria.

| Test | Memory (pass/fail) | | |
|------|--------------------|------|------|
| | | | |
| | Pass | Pass | Pass |
| | Pass | Pass | Pass |
| | Pass | Pass | Pass |

EXHIBIT B (cont.)

| | | | | |
|--|---------------------|--|---------------------------|------------------------|
|  Medtronic | <i>Neurological</i> | Document Number 288117-70205 | Rev/Version 1.0 | Sht 20 of 49 |
| Title: Neuro Patient Programmer Platform Electrical DVT Report | | | | |

4.3.2 Real-Time Clock Backup Test

4.3.2.1 Objective

To verify the real-time clock backup meets the requirements specified in the *Internal Resources* section of the PEM Electrical Specification.

4.3.2.2 Method and Equipment

4.3.2.3 Test Cases

There is one test case below:

| Parameter | Test Value | Units |
|-----------|------------|-------|
| | | |

4.3.2.4 Acceptance Criteria

| Test Case | Min Time w/o power (min) |
|-----------|--------------------------------|
| | |

4.3.2.5 Test Setup

- 1.
- 2.
- 3.


4.3.2.6 Test Procedure

- 1.
- 2.
- 3.
- 4.
- 5.

4.3.2.7 RESULTS **PASS**

All devices met the acceptance criteria.

EXHIBIT B (cont.)

| | | | | |
|--|---------------------|---|----------------------------------|-------------------------------|
|  Medtronic | <i>Neurological</i> | Document Number 288117-70205 | Rev/Version 1.0 | Sht 21 of 49 |
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| Test | Real-Time Backup (pass/fail) | | |
|------|------------------------------|------|------|
| | | | |
| | Pass | Pass | Pass |

4.3.3 Real-Time Clock Accuracy Test

4.3.3.1 Objective

To verify the real-time clock accuracy meets the requirements specified in the *Internal Resources* section of the PEM Electrical Specification.

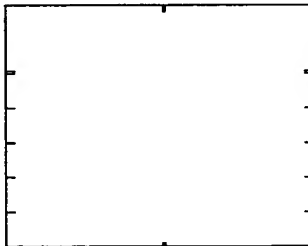
4.3.3.2 Method and Equipment

4.3.3.3 Test Cases

There are test cases (actually measurement points) using all combinations of test values below:

| Parameter | Test Value | Units |
|-----------|------------|-------|
| | | |

4.3.3.4 Acceptance Criteria



4.3.3.5 Test Setup

- 1.
- 2.


4.3.3.6 Test Procedure

- 1.
- 2.

4.3.3.7 RESULTS **PASS**

All devices met the acceptance criteria.

EXHIBIT B (cont.)

| | | | | |
|--|---------------------|---|----------------------------------|-------------------------------|
|  Medtronic | <i>Neurological</i> | Document Number 288117-70205 | Rev/Version 1.0 | Sht 22 of 49 |
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| | Real Time Clock Accuracy (seconds) | | | | | |
|--|------------------------------------|--|--|--|--|--|
| | | | | | | |
| | | | | | | |
| | | | | | | |
| | | | | | | |
| | | | | | | |
| | | | | | | |

4.3.4 A/D Measurements Test

4.3.4.1 Objective

To verify the A/D measurement accuracy meets the requirements specified in the *Internal Resources* section of the PEM Electrical Specification.

4.3.4.2 Method and Equipment

4.3.4.3 Test Cases

There are test cases using the test values below:

| Parameter | Test Values | Units |
|-----------|-------------|-------|
| | | |
| | | |
| | | |


4.3.4.4 Acceptance Criteria

| A/D Voltage | Test Value | Max Error (%) |
|-------------|------------|---------------|
| | | |
| | | |
| | | |

4.3.4.5 Test Setup

- 1.
- 2.
- 3.
- 4.

EXHIBIT B (cont.)

| | | | | |
|--|---------------------|---------------------------------|--------------------|-----------------|
|  Medtronic | <i>Neurological</i> | Document Number 288117-70205 | Rev/Version 1.0 | Sht 23 of 49 |
| Title: Neuro Patient Programmer Platform Electrical DVT Report | | | | |

5.

4.3.4.6 Test Procedure

1.

2.


3.

4.

4.3.4.7 RESULTS **PASS**

All devices met the acceptance criteria.

EXHIBIT B (cont.)

| | | | | |
|--|---------------------|---|----------------------------------|-------------------------------|
|  Medtronic | <i>Neurological</i> | Document Number 288117-70205 | Rev/Version 1.0 | Sht 24 of 49 |
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[illegible]

4.3.5 D/A Control Voltages Test

4.3.5.1 Objective


To verify the D/A accuracy meets the requirements specified in the *Internal Resources* section of the PEM Electrical Specification.

4.3.5.2 *Method and Equipment*

4.3.5.3 Test Cases

There are test cases using all combinations of test values below:

EXHIBIT B (cont.)

| | | | | |
|--|---------------------|--|---------------------------|------------------------|
|  Medtronic | <i>Neurological</i> | Document Number 288117-70205 | Rev/Version 1.0 | Sht 25 of 49 |
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| Parameter | Test Value | Units |
|-----------|------------|-------|
| | | |

4.3.5.4 Acceptance Criteria

| D/A Voltage | Measurement point | Max % Error |
|-------------|-------------------|-------------|
| | | |

4.3.5.5 Test Setup

- 1.
- 2.
- 3.
- 4.

4.3.5.6 Test Procedure

- 1.
- 2.
- 3.

4.3.5.7 RESULTS **PASS**

All devices met the acceptance criteria.

[illegible]


4.4 Transmit Telemetry (Downlink) Tests

4.4.1 Magnetic Field Intensity Test

4.4.1.1 Objective

To verify downlink magnetic field intensity meets the requirements specified in the *Transmit Telemetry (Downlink)* section of the PEM Electrical Specification.

EXHIBIT B (cont.)

| | | | | |
|--|---------------------|---|----------------------------------|-------------------------------|
|  Medtronic | <i>Neurological</i> | Document Number 288117-70205 | Rev/Version 1.0 | Sht 26 of 49 |
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4.4.1.2 Method and Equipment

4.4.1.3 Test Cases

There are test cases at kHz using all combinations of test values below:

| Age Group | Percentage of Respondents |
|-----------|---------------------------|
| 18-29 | 65% |
| 30-49 | 75% |
| 50-69 | 80% |
| 70+ | 85% |

4.4.1.4 Acceptance Criteria

4.4.1.5 Test Setup


- 1.
- 2.
- 3.
- 4.
- 5.

4.4.1.6 Test Procedure

- 1.
- 2.

3.
4.

EXHIBIT B (cont.)

| | | | | |
|--|---------------------|--|---------------------------|------------------------|
|  Medtronic | <i>Neurological</i> | Document Number 288117-70205 | Rev/Version 1.0 | Sht 27 of 49 |
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5.

4.4.1.7 RESULTS **PASS**

All devices met the acceptance criteria.

| | Magnetic Field Intensity (A/m) |
|--|--------------------------------|
| | |
| | |
| | |
| | |
| | |
| | |
| | |
| | |

4.4.2 **Burst Characteristics Test**

4.4.2.1 Objective

To verify downlink burst characteristics of width, rise time, fall time, frequency, and overshoot meet the requirements specified in the *Transmit Telemetry (Downlink)* section of the PEM Electrical Specification.


4.4.2.2 Method and Equipment

4.4.2.3 Test Cases

There are test cases using all combinations of test values below:

| Parameter | Test Values | Units |
|-----------|-------------|-------|
| | | |
| | | |
| | | |

EXHIBIT B (cont.)

| | | | | |
|--|---------------------|--|---------------------------|------------------------|
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4.4.2.4 Acceptance Criteria

| |
|--|
| |
|--|

4.4.2.5 Test Setup

- 1.
- 2.
- 3.
- 4.
- 5.

4.4.2.6 Test Procedure

- 1.
- 2.
- 3.
- 4.
- 5.


4.4.2.7 RESULTS **PASS**

All devices met the acceptance criteria.

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[illegible]

EXHIBIT B (cont.)

| | | | | |
|--|--------------|---------------------------------|--------------------|-----------------|
|  Medtronic | Neurological | Document Number 288117-70205 | Rev/Version 1.0 | Sht 30 of 49 |
| Title: Neuro Patient Programmer Platform Electrical DVT Report | | | | |

4.5 Receive Telemetry (Uplink) Tests

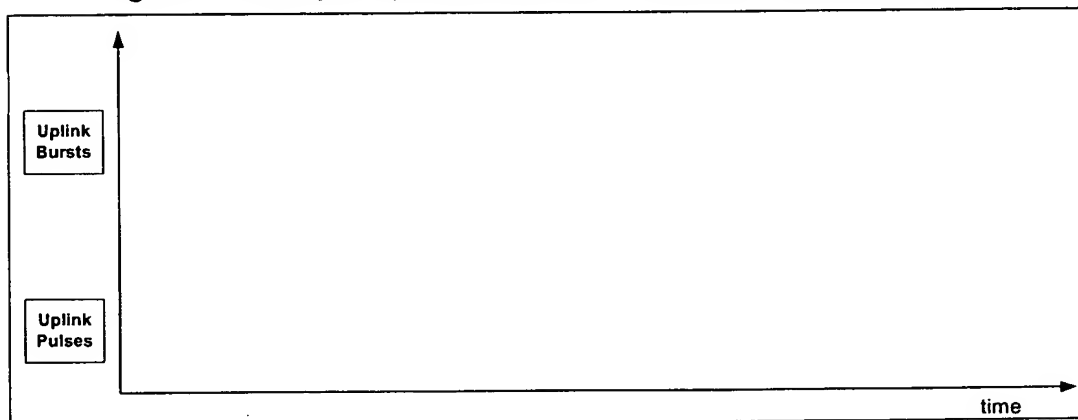
4.5.1 Detection Threshold Test

4.5.1.1 Objective

To verify uplink detection threshold (i.e. receiver sensitivity) meets the requirements specified in the *Receive Telemetry (Uplink)* section of the PEM Electrical Specification.

4.5.1.2 Method and Equipment

Figure 1: Example Uplink Detection Threshold Test Waveforms




4.5.1.3 Test Cases

There are test cases using all combinations of test values below:

| Parameter | Test Values | Units |
|-----------|-------------|-------|
| | | |
| | | |
| | | |
| | | |
| | | |

The supply voltage is 2.5 V.

EXHIBIT B (cont.)

| | | | | |
|--|---------------------|---|----------------------------------|-------------------------------|
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4.5.1.4 Acceptance Criteria

| Antenna | Telemetry Type | Detection Onset (Uplink dB) | Detection Threshold (Uplink dB) | Maximum Input Level (Uplink dB) |
|---------|----------------|-----------------------------|---------------------------------|---------------------------------|
| | | Max | Max | Max |
| | | | | |

4.5.1.5 Test Setup

- 1.
- 2.
- 3.
- 4.
- 5.

4.5.1.6 Test Procedure


- 1.
- 2.
- 3.
- 4.

4.5.1.7 RESULTS PASS

All devices met the acceptance criteria.

[illegible]

EXHIBIT B (cont.)

| | | | | |
|--|---------------------|---|----------------------------------|-------------------------------|
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| Antenna | Telemetry | Maximum Input Level (pass/fail) | | |
|---------|-----------|---------------------------------|------|------|
| | | | | |
| | | Pass | Pass | Pass |
| | | Pass | Pass | Pass |
| | | Pass | Pass | Pass |
| | | Pass | Pass | Pass |
| | | Pass | Pass | Pass |
| | | Pass | Pass | Pass |

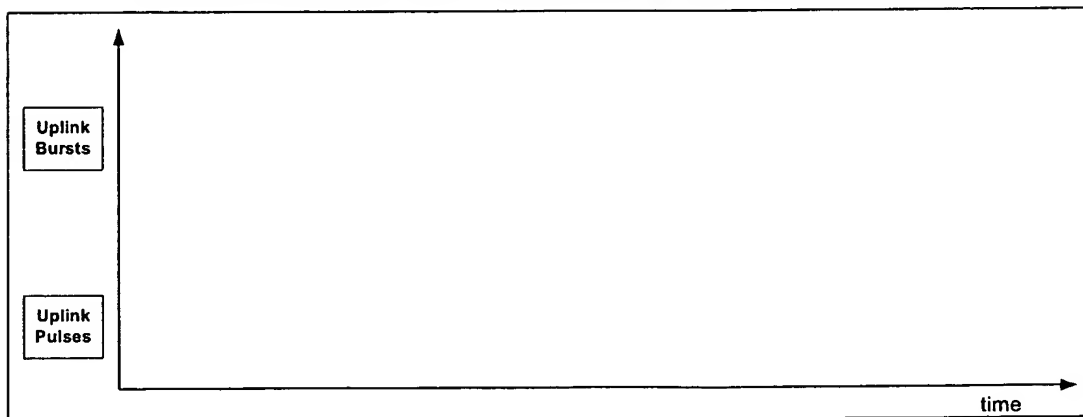
4.5.2 Detection Margin Test

4.5.2.1 Objective

To verify uplink detection margin meets the requirements specified in the *Receive Telemetry (Uplink)* section of the PEM Electrical Specification.

4.5.2.2 Method and Equipment


Figure 2: Example Uplink Detection Margin Test Waveforms



4.5.2.3 Test Cases

There are test cases using all combinations of test values below:

EXHIBIT B (cont.)

| | | | | | |
|---|------------------|---------------------|--|---------------------------|------------------------|
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| Parameter | Test Values | Units |
|-----------|-------------|-------|
| | | |
| | | |
| | | |
| | | |
| | | |

4.5.2.4 Acceptance Criteria

| Telemetry Type | Data Bursts | Amplitude A1 | Antenna | Detection Margin (Uplink dB) | |
|----------------|-------------|--------------|---------|------------------------------|-----|
| | | | | Min | Max |
| | | | | | |

4.5.2.5 Test Setup

- 1.
- 2.
- 3.
- 4.
- 5.

4.5.2.6 Test Procedure

- 1.
- 2.
- 3.
- 4.

4.5.2.7 RESULTS **PASS**

All devices met the acceptance criteria.

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4.5.3.2 Method and Equipment

EXHIBIT B (cont.)


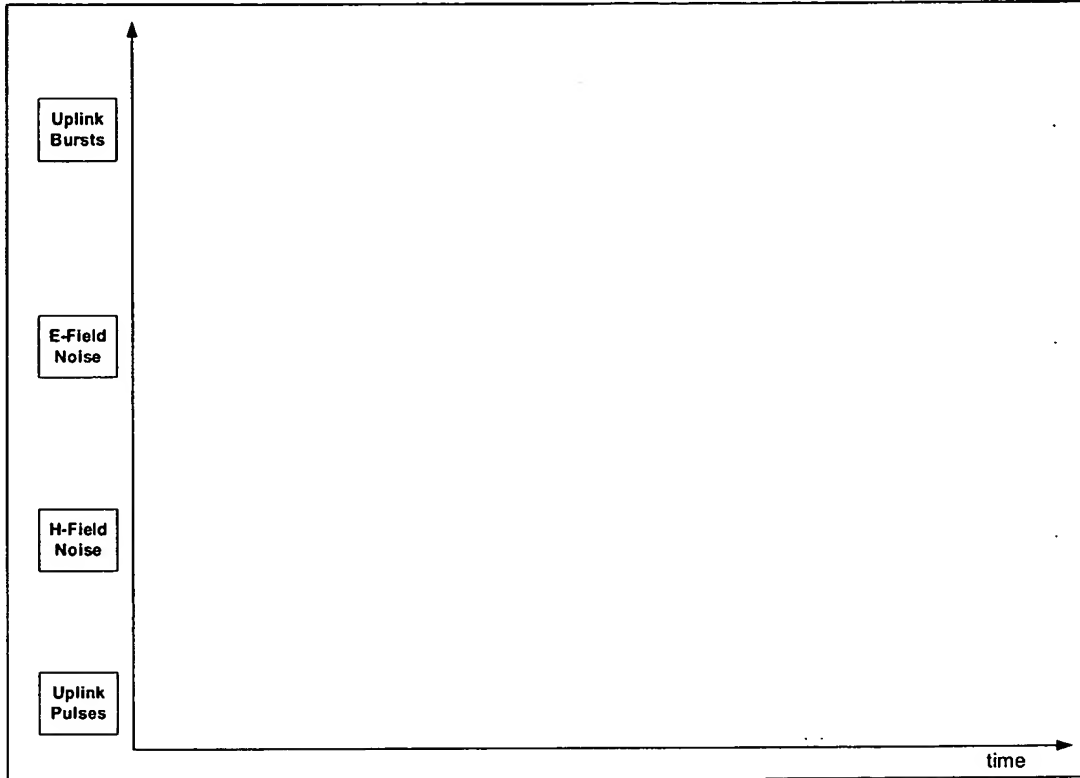
| | | | | |
|--|---------------------|--|---------------------------|------------------------|
|  Medtronic | <i>Neurological</i> | Document Number 288117-70205 | Rev/Version 1.0 | Sht 35 of 49 |
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Figure 3: Example Uplink Noise Immunity Test Waveforms




4.5.3.3 Test Cases

There are test cases using all combinations of test values below:

| Parameter | Test Values | Units |
|-----------|-------------|-------|
| | | |
| | | |
| | | |
| | | |

EXHIBIT B (cont.)

| | | | | |
|--|---------------------|--|---------------------------|-----------------|
|  Medtronic | <i>Neurological</i> | Document Number 288117-70205 | Rev/Version 1.0 | Sht 36 of 49 |
| Title: Neuro Patient Programmer Platform Electrical DVT Report | | | | |

4.5.3.4 Acceptance Criteria

| Telemetry Type | Uplink Level A1 (dB) | Antenna | Min E-Noise Immunity (dB) | Min H-Noise Immunity (dB) |
|----------------|----------------------|---------|---------------------------|---------------------------|
| | | | | |

4.5.3.5 Test Setup

- 1.
- 2.
- 3.
- 4.
- 5.
- 6.


4.5.3.6 Test Procedure

- 1.
- 2.
- 3.
- 4.
- 5.

4.5.3.7 RESULTS **PASS**

All devices met the acceptance criteria.

EXHIBIT B (cont.)

| | | | | |
|--|---------------------|---|----------------------------------|-------------------------------|
|  Medtronic | <i>Neurological</i> | Document Number 288117-70205 | Rev/Version 1.0 | Sht 37 of 49 |
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[illegible]


4.5.4 Signal Distortion Test

4.5.4.1 Objective

To verify uplink signal distortion meets the requirements specified in the *Receive Telemetry (Uplink)* section of the PEM Electrical Specification.

4.5.4.2 *Method and Equipment*

EXHIBIT B (cont.)

| | | | | |
|--|---------------------|---|----------------------------------|-------------------------------|
|  Medtronic | <i>Neurological</i> | Document Number 288117-70205 | Rev/Version 1.0 | Sht 38 of 49 |
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4.5.4.3 Test Cases

| Parameter | Test Values | Units |
|-----------|-------------|-------|
| | | |
| | | |
| | | |
| | | |
| | | |

There are test cases for Tel A, and test cases for Tel N.

4.5.4.4 Acceptance Criteria

| Telemetry Type | Uplink Level A1 (dB) | Antenna | Interval Distortion (μS) | Active/Idle Distortion (μS) |
|----------------|-------------------------|---------|------------------------------|---------------------------------|
| | | | | |

4.5.4.5 Test Setup

- 1.
- 2.
- 3.
- 4.
- 5.

4.5.4.6 Test Procedure

- 1.
- 2.
- 3.
- 4.

4.5.4.7 RESULTS **PASS**

All devices met the acceptance criteria.


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[illegible][illegible]

EXHIBIT B (cont.)

| | | | | |
|--|---------------------|---|----------------------------------|-------------------------------|
|  Medtronic | <i>Neurological</i> | Document Number 288117-70205 | Rev/Version 1.0 | Sht 40 of 49 |
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[illegible]

4.5.5 Turnaround Time Test

4.5.5.1 Objective

To verify uplink turnaround time meets the requirements specified in the *Receive Telemetry (Uplink)* section of the PEM Electrical Specification.


4.5.5.2 Method and Equipment

4.5.5.3 Test Cases

There are test cases using all combinations of test values below:

| Parameter | Test Values | Units |
|-----------|-------------|-------|
| | | |

EXHIBIT B (cont.)

| | | | | |
|--|---------------------|---|----------------------------------|-------------------------------|
|  Medtronic | <i>Neurological</i> | Document Number 288117-70205 | Rev/Version 1.0 | Sht 41 of 49 |
| Title: Neuro Patient Programmer Platform Electrical DVT Report | | | | |

4.5.5.4 Acceptance Criteria

| Supply Voltage | H-Bridge Drive Duty Cycle | Turnaround Time (mS) |
|----------------|---------------------------|-----------------------|
| | | |

4.5.5.5 Test Setup

- 1.
- 2.
- 3.

4.5.5.6 Test Procedure

- 1.
- 2.
- 3.
- 4.

4.5.5.7 RESULTS **PASS**

All devices met the acceptance criteria.

| | Turnaround Time (pass/fail) |
|------|-----------------------------|
| Test | |
| | |


4.5.6 Hold Drift Test

4.5.6.1 Objective

To verify the hold drift meets the requirements specified in the *Receive Telemetry (Uplink)* section of the PEM Electrical Specification.

4.5.6.2 Method and Equipment

EXHIBIT B (cont.)

| | | | | |
|--|---------------------|--|---------------------------|------------------------|
|  Medtronic | <i>Neurological</i> | Document Number 288117-70205 | Rev/Version 1.0 | Sht 42 of 49 |
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4.5.6.3 Test Cases

There is test case:

| Parameter | Uplink Level | Units |
|-----------|--------------|-------|
| | | |

4.5.6.4 Acceptance Criteria

| | |
|------------------------------------|----------------|
| Time after hold circuit enabled | Max Hold Drift |
| | |


4.5.6.5 Test Setup

- 1.
- 2.
- 3.

4.5.6.6 Test Procedure

- 1.
- 2.
- 3.
- 4.
- 5.
- 6.
- 7.
- 8.
- 9.
- 10

EXHIBIT B (cont.)

| | | | | | |
|---|------------------|---------------------|---------------------------------|--------------------|-----------------|
|  | Medtronic | <i>Neurological</i> | Document Number 288117-70205 | Rev/Version 1.0 | Sht 43 of 49 |
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4.5.6.7 RESULTS PASS

All devices met the acceptance criteria.

| Hold Drift (mV) |
|-----------------|
| |

4.5.7 New-Battery FET Test

4.5.7.1 Objective

To verify that enabling the new-battery FET circuit reduces the receiver noise floor (ambient RF energy detected by the receiver circuit) when new batteries are used.

4.5.7.2 Method and Equipment

4.5.7.3 Test Cases

There is test case:

| Parameter | Uplink Level | Units |
|-----------|--------------|-------|
| | | |


4.5.7.4 Acceptance Criteria

| Supply Voltage | New-Battery FET | RSSI Peak |
|----------------|-----------------|-----------|
| | | |

4.5.7.5 Test Setup

- 1.
- 2.
- 3.

EXHIBIT B (cont.)

| | | | | |
|--|---------------------|--|---------------------------|------------------------|
|  Medtronic | <i>Neurological</i> | Document Number 288117-70205 | Rev/Version 1.0 | Sht 44 of 49 |
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4.5.7.6 Test Procedure

- 1.
- 2.
- 3.
- 4.
- 5.
- 6.
- 7.

4.5.7.7 RESULTS **PASS**

All devices met the acceptance criteria.

| New-Battery FET (mV) | | | | | | | | | | | | | |
|----------------------|-----|------|---------|--|-----|-----|------|---------|--|-----|-----|------|---------|
| Min | Max | Mean | Std dev | | Min | Max | Mean | Std dev | | Min | Max | Mean | Std dev |
| | | | | | | | | | | | | | |

4.6 Telemetry Performance Tests


4.6.1 Telemetry Map Area at a Fixed Distance Test

4.6.1.1 Objective

To verify telemetry performance in terms of map area at a fixed distance meets the requirements specified in the *Telemetry Performance* section of the PEM Electrical Specification.

4.6.1.2 Method and Equipment

EXHIBIT B (cont.)

| | | | | |
|--|---------------------|--|---------------------------|------------------------|
|  Medtronic | <i>Neurological</i> | Document Number 288117-70205 | Rev/Version 1.0 | Sht 45 of 49 |
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4.6.1.3 Test Cases

| Parameter | Test Values | Units |
|-----------|-------------|-------|
| | | |
| | | |
| | | |
| | | |
| | | |
| | | |
| | | |
| | | |
| | | |

There are test cases.

4.6.1.4 Acceptance Criteria

| IPG | Antenna | Map Area @ 5cm |
|-----|---------|-------------------|
| | | |
| | | |
| | | |

4.6.1.5 Test Setup


- 1.
- 2.

4.6.1.6 Test Procedure

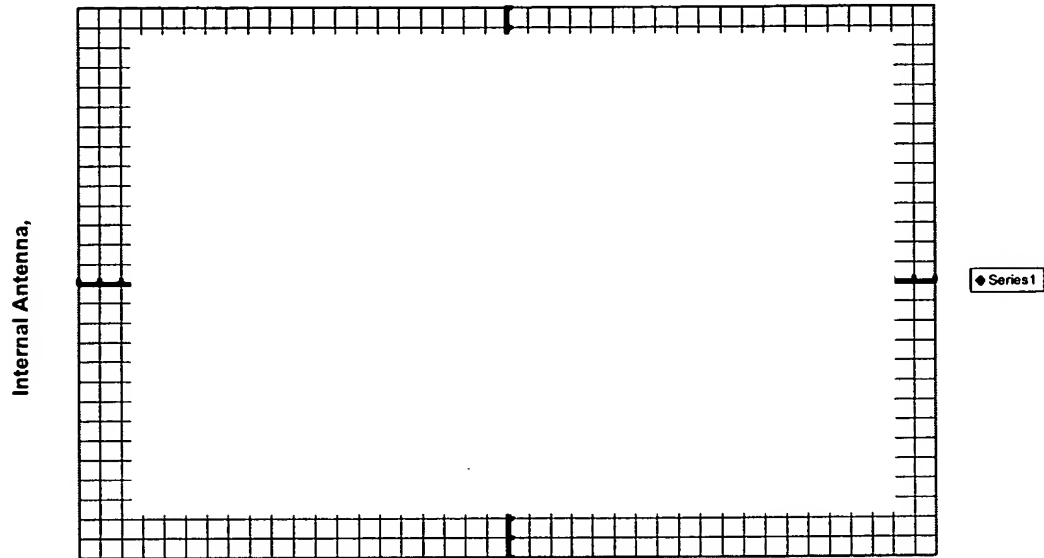
- 1.
- 2.
- 3.
- 4.
- 5.
- 6.
- 7.
- 8.

4.6.1.7 RESULTS **PASS**

EXHIBIT B (cont.)

| | | | | |
|--|---------------------|--|---------------------------|------------------------|
|  Medtronic | <i>Neurological</i> | Document Number 288117-70205 | Rev/Version 1.0 | Sht 46 of 49 |
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4.6.1.7.1 Internal Antenna Map @



4.6.1.7.2 Internal Antenna @

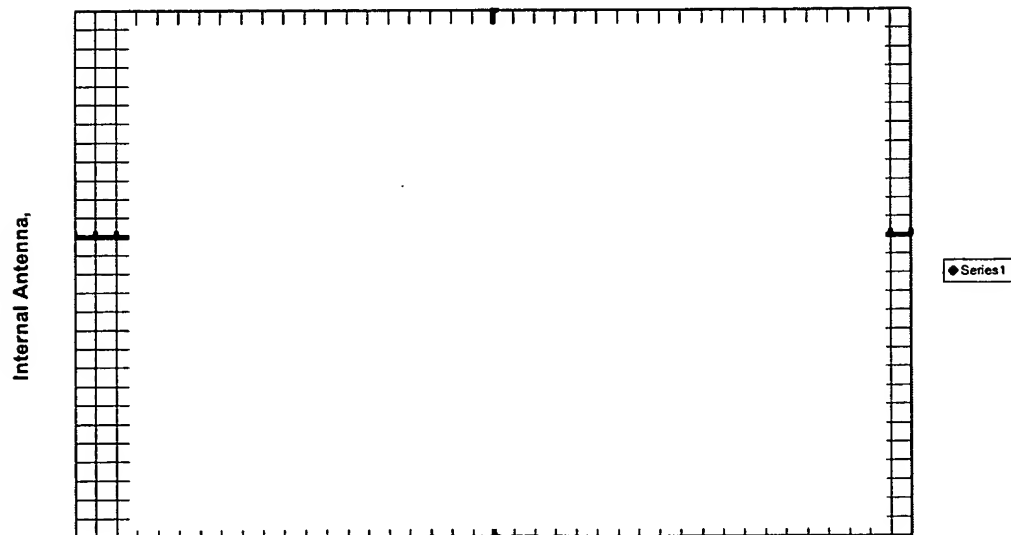

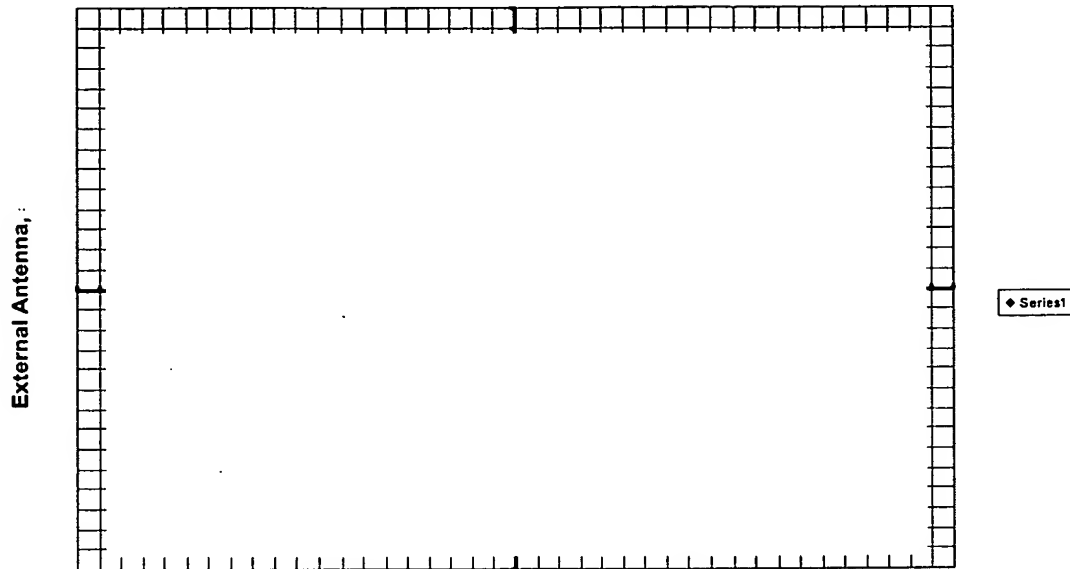


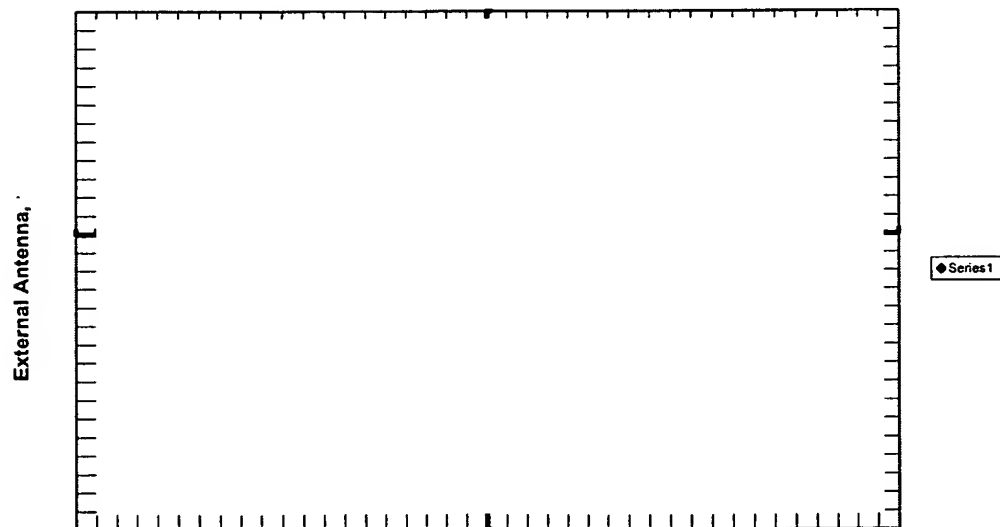
EXHIBIT B (cont.)

| | | | | |
|--|---------------------|---------------------------------|--------------------|-----------------|
|  Medtronic | <i>Neurological</i> | Document Number 288117-70205 | Rev/Version 1.0 | Sht 47 of 49 |
| Title: Neuro Patient Programmer Platform Electrical DVT Report | | | | |

4.6.1.7.3 External Antenna Map @




4.6.1.7.4 External Antenna @

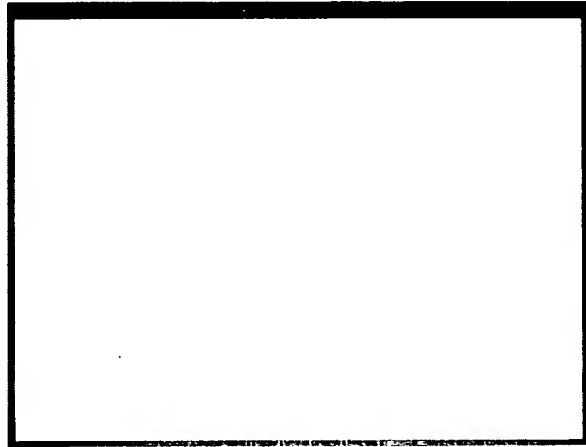


4.6.1.7.5 Photo of test fixture showing

EXHIBIT B (cont.)

| | | | | |
|--|---------------------|--|---------------------------|------------------------|
|  Medtronic | <i>Neurological</i> | Document Number 288117-70205 | Rev/Version 1.0 | Sht 48 of 49 |
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in this photo.



4.6.1.7.6 Photo of



EXHIBIT B (cont.)

| | | | | |
|--|---------------------|--|---------------------------|------------------------|
|  Medtronic | <i>Neurological</i> | Document Number 288117-70205 | Rev/Version 1.0 | Sht 49 of 49 |
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5 COMPLETION

This paragraph concludes this test specification.



Test Path #1 from DVT Plan 288117-70020 Section 7.0**DVT Pre-Test Performed to verify operational units.**

| Serial Number | Buttons | | Audio | LCD | Battery contact | Battery Door | Real time | | IR | Backlight | Communication | Results |
|---------------|-------------|---------|-------|-----|-----------------|--------------|-----------|-------|----|-----------|---------------|---------|
| | operational | Buttons | | | | | clock | clock | | | | |
| NJD000018P | x | | x | x | x | x | x | x | x | x | x | OK |
| NJD000019P | x | | x | x | x | x | x | x | x | x | x | OK |
| NJD000020P | x | | x | x | x | x | x | x | x | x | x | OK |
| NJD000022P | x | | x | x | x | x | x | x | x | x | x | OK |
| NJD000024P | x | | x | x | x | x | x | x | x | x | x | OK |
| NJD000025P | x | | x | x | x | x | x | x | x | x | x | OK |
| NJD000026P | x | | x | x | x | x | x | x | x | x | x | OK |
| NJD000028P | x | | x | x | x | x | x | x | x | x | x | OK |
| NJD000031P | x | | x | x | x | x | x | x | x | x | x | OK |
| NJD000033P | x | | x | x | x | x | x | x | x | x | x | OK |
| NJD000034P | x | | x | x | x | x | x | x | x | x | x | OK |
| NJD000035P | x | | x | x | x | x | x | x | x | x | x | OK |
| NJD000036P | x | | x | x | x | x | x | x | x | x | x | OK |
| NJD000037P | x | | x | x | x | x | x | x | x | x | x | OK |
| NJD000077P | x | | x | x | x | x | x | x | x | x | x | OK |
| NJD000078P | x | | x | x | x | x | x | x | x | x | x | OK |
| NJD000079P | x | | x | x | x | x | x | x | x | x | x | OK |
| NJD000080P | x | | x | x | x | x | x | x | x | x | x | OK |
| NJD000138P | x | | x | x | x | x | x | x | x | x | x | OK |
| NJD000139P | x | | x | x | x | x | x | x | x | x | x | OK |
| NJD000140P | x | | x | x | x | x | x | x | x | x | x | OK |
| NJD000149P | x | | x | x | x | x | x | x | x | x | x | OK |

Testing performed by

Date:

23-May-02

EQUIPMENT:

Test Path #1

DVT Test Data for 288117-70020

Revision 4.0

SUMMARY SHEET

PAR# 5365

TEST PLAN: 288117-70020

TECH:

Patient Programmer for Neuro devices.

DATE: 29 MAY 02

INITIAL VISUAL & ELECTRICAL

| SERIAL# | VISUAL | Requestor did functional |
|------------|--------|-----------------------------|
| NJD000018P | O.K. | X |
| NJD000019P | O.K. | X |
| NJD000020P | O.K. | X |
| NJD000022P | O.K. | X |
| NJD000024P | O.K. | X |
| NJD000025P | O.K. | X |
| NJD000026P | O.K. | X |
| NJD000028P | O.K. | X |
| NJD000031P | O.K. | X |
| NJD000033P | O.K. | X |
| NJD000034P | O.K. | X |
| NJD000035P | O.K. | X |
| NJD000036P | O.K. | X |
| NJD000037P | O.K. | X |
| NJD000077P | O.K. | X |
| NJD000078P | O.K. | X |
| NJD000079P | O.K. | X |
| NJD000080P | O.K. | X |
| NJD000138P | O.K. | X |
| NJD000139P | O.K. | X |
| NJD000140P | O.K. | X |
| NJD000149P | O.K. | X |
| 3-Jun | | |

RESULTS: NO ANOMALIES NOTED

Exhibit D (cont.)

288117-70183

Test Path #1

DVT Test Data for 288117-70020

Revision 4.0

SUMMARY SHEET

TEST PLAN: 288117-70020

Patient Programmer for Neuro devices.

Life cycle of battery contacts and door, and external antenna jack.

DATE:

19-Jun-02

Subject samples

288117-70020 test

| | Battery Door | Battery External Contact Antenna | Dimension | Weight w/o batteries | 2 AA batteries | Total Weight |
|---------------|--------------|----------------------------------|--------------|----------------------|----------------|--------------|
| Serial Number | 6.3.3 cycles | 6.3.4 cycles | 6.3.5 cycles | 6.3.1 | 6.3.2 | 6.3.1 |
| Tested by: | | | | | | |
| Length | | | | | | |
| Width | | | | | | |
| Ht. | | | | | | |
| oz. | | | | | | |
| oz. | | | | | | |
| oz. | | | | | | |

| | |
|------------|--|
| NJD000018P | |
| NJD000019P | |
| NJD000020P | |
| NJD000022P | |
| NJD000024P | |
| NJD000025P | |
| NJD000026P | |
| NJD000028P | |
| NJD000031P | |
| NJD000033P | |
| NJD000034P | |
| NJD000035P | |
| NJD000036P | |
| NJD000037P | |
| NJD000077P | |
| NJD000078P | |
| NJD000079P | |
| NJD000080P | |
| NJD000138P | |
| NJD000139P | |
| NJD000140P | |
| NJD000149P | |

Average

Test Path #1

DVT Test Data for 288117-70020

Revision 4.0

Std Dev

Dimensions per print 502814

EQUIPMENT:

Exhibit D (cont.)

288117-70183

Page 4 of 29

SUMMARY SHEET

PAR# 5365

TEST PLAN: 288117-70020

TECH:

Patient Programmer for Neuro devices.

Storage Temperature paragraph 6.2.2 of test plan.

DATE:

19-Jun-02 All Functional Testing done per 6.1 except backlight and IR port.

Subject samples to low temp. storage of degrees F for hours then degrees F for hours.
Functional test samples post each temperature storage.

| Serial # | Functional | Functional |
|----------------|------------|------------|
| NJD000018P | | |
| NJD000019P | | |
| NJD000020P | | |
| NJD000022P | | |
| NJD000024P | | |
| NJD000025P | | |
| NJD000026P | | |
| NJD000028P | | |
| NJD000031P | | |
| NJD000033P | | |
| NJD000034P | | |
| NJD000035P | | |
| NJD000036P | | |
| NJD000037P | | |
| NJD000077P | | |
| NJD000078P | | |
| NJD000079P | | |
| NJD000080P | | |
| NJD000138P | | |
| NJD000139P | | |
| NJD000140P | | |
| NJD000149P | | |
| Date: Complete | 18-Jun | 19-Jun |

NOTES:

A=

B=

C=

Results:

Test Path #1

DVT Test Data for 288117-70020

Revision 4.0

EQUIPMENT:

Exhibit D (cont.)

288117-70183

Page 6 of 29

SUMMARY SHEET

PAR# 5365

TEST PLAN: 288117-70020

TECH:

Patient Programmer for Neuro devices. Operating Temperature paragraph 6.2.1 of test plan.

DATE: 4-Jun-02 All Functional Testing done per 6.1 except backlight and IR port.

Subject samples to Low temp. storage of degrees F for hours then degrees F for hours.

| Serial # | Low temp. | Functional | High Temp. | Functional |
|----------------|-----------|------------|------------|------------|
| NJD000018P | | | | |
| NJD000019P | | | | |
| NJD000020P | | | | |
| NJD000022P | | | | |
| NJD000024P | | | | |
| NJD000025P | | | | |
| NJD000026P | | | | |
| NJD000028P | | | | |
| NJD000031P | | | | |
| NJD000033P | | | | |
| NJD000034P | | | | |
| NJD000035P | | | | |
| NJD000036P | | | | |
| NJD000037P | | | | |
| NJD000077P | | | | |
| NJD000078P | | | | |
| NJD000079P | | | | |
| NJD000080P | | | | |
| NJD000138P | | | | |
| NJD000139P | | | | |
| NJD000140P | | | | |
| NJD000149P | | | | |
| Date: Complete | 4-Jun | 4-Jun | 5-Jun | 5-Jun |

NOTES: A=

Results:

EQUIPMENT:

Test Path #1

DVT Test Data for 288117-70020

Revision 4.0

SUMMARY SHEET

PAR# 5365

TEST PLAN: 288117-70020

TECH:

Patient Programmer for Neuro devices.

DATE:

20-Jun-02 Thermal Shock paragraph 6.2.3 of test plan.

Subject samples to cycles of degrees F, then degrees F, then 1

Dwell at each temperature for 1 hour. All Functional Testing done per 6.1 except backlight and IR port.

| Serial # | Thermal Shock | Functional Testing | Visual |
|-------------|---------------|--------------------|--------|
| NJD0000018P | | | |
| NJD0000019P | | | |
| NJD0000020P | | | |
| NJD0000022P | | | |
| NJD0000024P | | | |
| NJD0000025P | | | |
| NJD0000026P | | | |
| NJD0000028P | | | |
| NJD0000031P | | | |
| NJD0000033P | | | |
| NJD0000034P | | | |
| NJD0000035P | | | |
| NJD0000036P | | | |
| NJD0000037P | | | |
| NJD0000077P | | | |
| NJD0000078P | | | |
| NJD0000079P | | | |
| NJD0000080P | | | |
| NJD000138P | | | |
| NJD000139P | | | |
| NJD000140P | | | |
| NJD000149P | | | |

NOTES: A=

RESULTS:

EQUIPMENT:

Test Path #1

DVT Test Data for 288117-70020

Revision 4.0

PAR# 5365

TEST PLAN: 288117-70020

SUMMARY SHEET

TECH:

Patient Programmer for Neuro devices.

DATE:

21-Jun-02 Chemical Resistance paragraph 6.2.7 of test plan.

Subject samples to

| Serial # | Chemical Testing | Visual |
|------------|---------------------|--------|
| NJD000018P | | |
| NJD000019P | | |
| NJD000020P | | |
| NJD000022P | | |
| NJD000024P | | |
| NJD000025P | | |
| NJD000026P | | |
| NJD000028P | | |
| NJD000031P | | |
| NJD000033P | | |
| NJD000034P | | |
| NJD000035P | | |
| NJD000036P | | |
| NJD000037P | | |
| NJD000077P | | |
| NJD000078P | | |
| NJD000079P | | |
| NJD000080P | | |
| NJD000138P | | |
| NJD000139P | | |
| NJD000140P | | |
| NJD000149P | | |

RESULTS:

EQUIPMENT:

288117-70183

Test Path #2 from DVT Plan 288117-70020 Section 7.0

DVT Pre-Test Performed to verify operational units.

| Serial Number | Buttons | | Audio | LCD | Battery | | Battery Door | Real time | | IR | Backlight | Communicatio | | Results |
|---------------|-------------|---------|-------|-----|---------|---------|--------------|-----------|-------|----|-----------|--------------|---|---------|
| | operational | Buttons | | | contact | contact | | clock | clock | | | n | n | |
| NJD000109P | x | x | x | x | x | x | x | x | x | x | x | x | x | OK |
| NJD000110P | x | x | x | x | x | x | x | x | x | x | x | x | x | OK |
| NJD000111P | x | x | x | x | x | x | x | x | x | x | x | x | x | OK |
| NJD000113P | x | x | x | x | x | x | x | x | x | x | x | x | x | OK |
| NJD000114P | x | x | x | x | x | x | x | x | x | x | x | x | x | OK |
| NJD000116P | x | x | x | x | x | x | x | x | x | x | x | x | x | OK |
| NJD000119P | x | x | x | x | x | x | x | x | x | x | x | x | x | OK |
| NJD000120P | x | x | x | x | x | x | x | x | x | x | x | x | x | OK |
| NJD000121P | x | x | x | x | x | x | x | x | x | x | x | x | x | OK |
| NJD000122P | x | x | x | x | x | x | x | x | x | x | x | x | x | OK |
| NJD000123P | x | x | x | x | x | x | x | x | x | x | x | x | x | OK |
| NJD000124P | x | x | x | x | x | x | x | x | x | x | x | x | x | OK |
| NJD000126P | x | x | x | x | x | x | x | x | x | x | x | x | x | OK |
| NJD000127P | x | x | x | x | x | x | x | x | x | x | x | x | x | OK |
| NJD000128P | x | x | x | x | x | x | x | x | x | x | x | x | x | OK |
| NJD000129P | x | x | x | x | x | x | x | x | x | x | x | x | x | OK |
| NJD000130P | x | x | x | x | x | x | x | x | x | x | x | x | x | OK |
| NJD000131P | x | x | x | x | x | x | x | x | x | x | x | x | x | OK |
| NJD000133P | x | x | x | x | x | x | x | x | x | x | x | x | x | OK |
| NJD000134P | x | x | x | x | x | x | x | x | x | x | x | x | x | OK |
| NJD000136P | x | x | x | x | x | x | x | x | x | x | x | x | x | OK |
| NJD000137P | x | x | x | x | x | x | x | x | x | x | x | x | x | OK |

Testing performed by

Date:

23-May-02

EQUIPMENT: I

I

Test Path #2

DVT Test Data for 288117-70020

Revision 2.0

SUMMARY SHEET

PAR# 5365

TEST PLAN: 288117-70020

TECH:

Patient Programmer for Neuro devices.

DATE: 29 MAY 02

INITIAL VISUAL & ELECTRICAL

| SERIAL# | VISUAL | Requestor did functional |
|------------|--------|-----------------------------|
| NJD000109P | O.K. | X |
| NJD000110P | O.K. | X |
| NJD000111P | O.K. | X |
| NJD000113P | O.K. | X |
| NJD000114P | O.K. | X |
| NJD000116P | O.K. | X |
| NJD000119P | O.K. | X |
| NJD000120P | O.K. | X |
| NJD000121P | O.K. | X |
| NJD000122P | O.K. | X |
| NJD000123P | O.K. | X |
| NJD000124P | O.K. | X |
| NJD000126P | O.K. | X |
| NJD000127P | O.K. | X |
| NJD000128P | O.K. | X |
| NJD000129P | O.K. | X |
| NJD000130P | O.K. | X |
| NJD000131P | O.K. | X |
| NJD000133P | O.K. | X |
| NJD000134P | O.K. | X |
| NJD000136P | O.K. | X |
| NJD000137P | O.K. | X |
| | 29-May | |

RESULTS:

Exhibit D (cont.)

288117-70183

Test Path #2

DVT Test Data for 288117-70020

Revision 2.0

PAR# 5365

TEST PLAN: 288117-70020

SUMMARY SHEET

TECH:

Patient Programmer for Neuro devices.

Broad Band Random Vibration paragraph 6.2.4 of test plan.

DATE:

4-Jun-02

All Functional Testing done per 6.1 except backlight and IR port.

Subject samples to

| SERIAL # | Back down | Visual | R. side dow | Visual | Top up | Visual | Functional | Observations |
|----------------|-----------|--------|-------------|--------|--------|--------|------------|--------------|
| NJD000109P | | | | | | | | |
| NJD000110P | | | | | | | | |
| NJD000111P | | | | | | | | |
| NJD000113P | | | | | | | | |
| NJD000114P | | | | | | | | |
| NJD000116P | | | | | | | | |
| NJD000119P | | | | | | | | |
| NJD000120P | | | | | | | | |
| NJD000121P | | | | | | | | |
| NJD000122P | | | | | | | | |
| NJD000123P | | | | | | | | |
| NJD000124P | | | | | | | | |
| NJD000126P | | | | | | | | |
| NJD000127P | | | | | | | | |
| NJD000128P | | | | | | | | |
| NJD000129P | | | | | | | | |
| NJD000130P | | | | | | | | |
| NJD000131P | | | | | | | | |
| NJD000133P | | | | | | | | |
| NJD000134P | | | | | | | | |
| NJD000136P | | | | | | | | |
| NJD000137P | | | | | | | | |
| Date Completed | 7-Jun | 7-Jun | 7-Jun | 7-Jun | 7-Jun | 7-Jun | 13-Jun | |

NOTES:

A=

B=

C=

RESULTS:

EQUIPMENT:

288117-70183

Test Path #2

DVT Test Data for 288117-70020

Revision 2.0

SUMMARY SHEET

PAR# 5365

TEST PLAN: 288117-70020

TECH: ROY POPE

Patient Programmer for Neuro devices.

Mechanical Shock paragraph 6.2.5 of test plan.

DATE:

20-Jun-02

All Functional Testing done per 6.1 except backlight and IR port.

Subject samples to

| SERIAL# | Front | Back | Top | Bottom | Left side | Right side | Testing |
|------------|-------|------|-----|--------|-----------|------------|---------|
| NJD000109P | | | | | | | |
| NJD000110P | | | | | | | |
| NJD000111P | | | | | | | |
| NJD000113P | | | | | | | |
| NJD000114P | | | | | | | |
| NJD000116P | | | | | | | |
| NJD000119P | | | | | | | |
| NJD000120P | | | | | | | |
| NJD000121P | | | | | | | |
| NJD000122P | | | | | | | |
| NJD000123P | | | | | | | |
| NJD000124P | | | | | | | |
| NJD000126P | | | | | | | |
| NJD000127P | | | | | | | |
| NJD000128P | | | | | | | |
| NJD000129P | | | | | | | |
| NJD000130P | | | | | | | |
| NJD000131P | | | | | | | |
| NJD000133P | | | | | | | |
| NJD000134P | | | | | | | |
| NJD000136P | | | | | | | |
| NJD000137P | | | | | | | |

NOTES:

A=

B=

RESULTS:

EQUIPMENT:

Test Path #3 from DVT Plan 288117-70020 Section 7.0**DVT Pre-Test Performed to verify operational units.**

| Serial Number | Buttons operational | Audio | LCD | Battery contact | Battery Door | Real time clock | IR | Backlight | Communication | Results |
|---------------|------------------------|-------|-----|--------------------|-----------------|--------------------|----|-----------|---------------|---------|
| NJD000081P | x | x | x | x | x | x | x | x | x | OK |
| NJD000082P | x | x | x | x | x | x | x | x | x | OK |
| NJD000083P | x | x | x | x | x | x | x | x | x | OK |
| NJD000084P | x | x | x | x | x | x | x | x | x | OK |
| NJD000086P | x | x | x | x | x | x | x | x | x | OK |
| NJD000087P | x | x | x | x | x | x | x | x | x | OK |
| NJD000089P | x | x | x | x | x | x | x | x | x | OK |
| NJD000092P | x | x | x | x | x | x | x | x | x | OK |
| NJD000093P | x | x | x | x | x | x | x | x | x | OK |
| NJD000094P | x | x | x | x | x | x | x | x | x | OK |
| NJD000096P | x | x | x | x | x | x | x | x | x | OK |
| NJD000097P | x | x | x | x | x | x | x | x | x | OK |
| NJD000098P | x | x | x | x | x | x | x | x | x | OK |
| NJD000099P | x | x | x | x | x | x | x | x | x | OK |
| NJD000100P | x | x | x | x | x | x | x | x | x | OK |
| NJD000101P | x | x | x | x | x | x | x | x | x | OK |
| NJD000102P | x | x | x | x | x | x | x | x | x | OK |
| NJD000103P | x | x | x | x | x | x | x | x | x | OK |
| NJD000104P | x | x | x | x | x | x | x | x | x | OK |
| NJD000106P | x | x | x | x | x | x | x | x | x | OK |
| NJD000107P | x | x | x | x | x | x | x | x | x | OK |
| NJD000108P | x | x | x | x | x | x | x | x | x | OK |

Testing performed by

Date:

23-May-02

EQUIPMENT: I

I

PAR# 5365

TEST PLAN: 288117-70020

TECH:

Patient Programmer for Neuro devices.

DATE: 29 MAY 02

INITIAL VISUAL & ELECTRICAL

| SERIAL# | VISUAL | Requestor did functional |
|----------------|--------|-----------------------------|
| NJD000081P | O.K. | X |
| NJD000082P | O.K. | X |
| NJD000083P | O.K. | X |
| NJD000084P | O.K. | X |
| NJD000086P | O.K. | X |
| NJD000087P | O.K. | X |
| NJD000089P | O.K. | X |
| NJD000092P | O.K. | X |
| NJD000093P | O.K. | X |
| NJD000094P | O.K. | X |
| NJD000096P | O.K. | X |
| NJD000097P | O.K. | X |
| NJD000098P | O.K. | X |
| NJD000099P | O.K. | X |
| NJD000100P | O.K. | X |
| NJD000101P | O.K. | X |
| NJD000102P | O.K. | X |
| NJD000103P | O.K. | X |
| NJD000104P | O.K. | X |
| NJD000106P | O.K. | X |
| NJD000107P | O.K. | X |
| NJD000108P | O.K. | X |
| Date: Complete | 29-May | |

RESULTS: NO ANOMALIES NOTED

PAR# 5365

TEST PLAN: 288117-70020

SUMMARY SHEET

TECH:

Patient Programmer for Neuro devices.

DATE: 29-May-02 All Functional Testing done per 6.1 except backlight and IR port.

Subject samples to degrees F and RH for days. Test samples per request days.

| SERIAL# | 3-Jun | 3-Jun | 4-Jun | 4-Jun | 19-Jun | 19-Jun |
|----------------|-------|-------|-------|-------|--------|--------|
| NJD000081P | | | | | | |
| NJD000082P | | | | | | |
| NJD000083P | | | | | | |
| NJD000084P | | | | | | |
| NJD000086P | | | | | | |
| NJD000087P | | | | | | |
| NJD000089P | | | | | | |
| NJD000092P | | | | | | |
| NJD000093P | | | | | | |
| NJD000094P | | | | | | |
| NJD000096P | | | | | | |
| NJD000097P | | | | | | |
| NJD000098P | | | | | | |
| NJD000099P | | | | | | |
| NJD000100P | | | | | | |
| NJD000101P | | | | | | |
| NJD000102P | | | | | | |
| NJD000103P | | | | | | |
| NJD000104P | | | | | | |
| NJD000106P | | | | | | |
| NJD000107P | | | | | | |
| NJD000108P | | | | | | |
| Date: Complete | 3-Jun | 3-Jun | 4-Jun | 4-Jun | 19-Jun | 19-Jun |

NOTES:

A=
B=
C=
D=

RESULTS:

E=
F=
G=
H=

EQUIPMENT:

I=

Exhibit D (cont.)

Section 6.3.6 Button Endurance - Specification for KSS321G, used for
... buttons (
Life Cycle data show life expectancy of

Exhibit D (cont.)

Other Data

DVT Test Data for 288117-70020

Revision 4.0

Section 6.3.8 Flamability - Both top and bottom housings are made from

Other Data

DVT Test Data for 288117-70020

Revision 4.0

Section 6.3.6 - Button Endurance - Specification for KSC621- Used for
top buttons (
Life Cycle data show life expectancy

Exhibit D (cont.)

Other Data

DVT Test Data for 288117-70020

Revision 4.0

Section 6.3.6 - Button Endurance - Specification for F
Used for
Life Cycle data show
life expectancy of

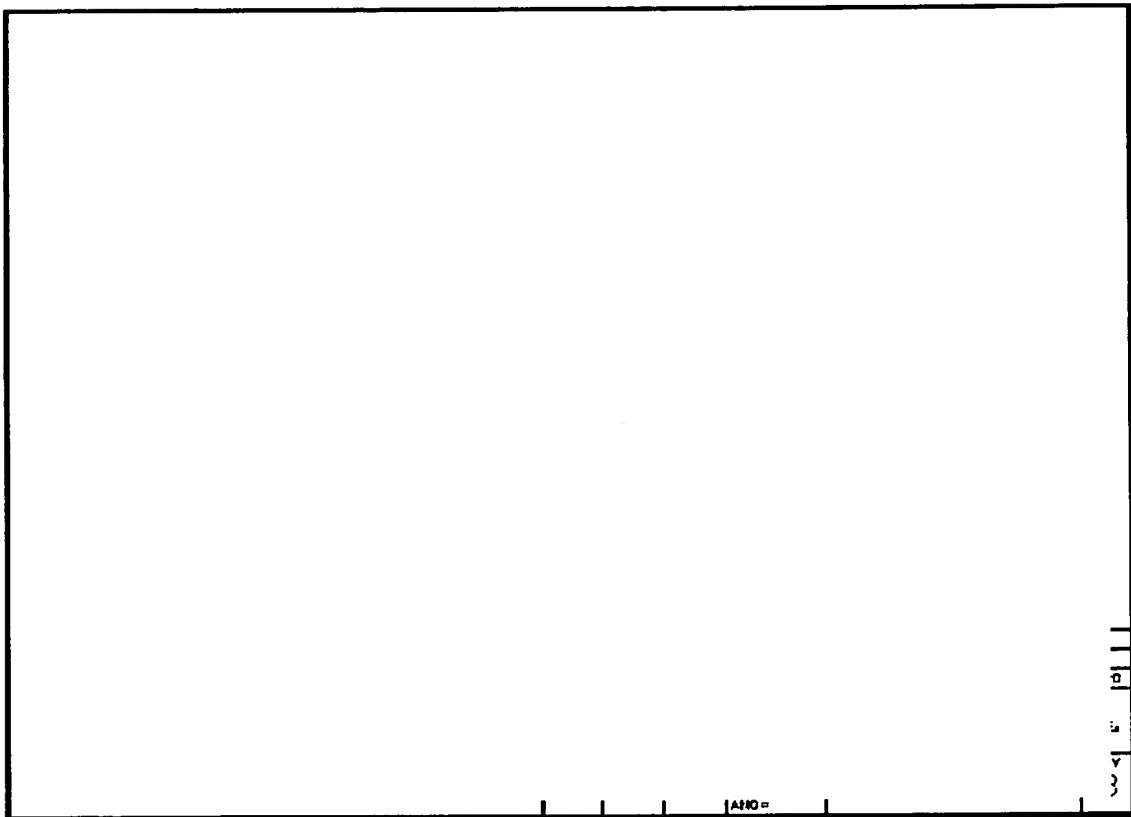


Exhibit D (cont.)

Other Data

DVT Test Data for 288117-70020

Revision 4.0

Blank Page

Exhibit D (cont.)

Other Data

DVT Test Data for 288117-70020

Revision 4.0

Exhibit D (cont.)

Other Data

DVT Test Data for 288117-70020

Revision 4.0

Section 6.3.7 Scratch resistance -



Exhibit D (cont.)

Other Data

DVT Test Data for 288117-70020

Revision 4.0

Exhibit D (cont.)

Other Data

DVT Test Data for 288117-70020

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